

REMARKS

Amendments

Claim 6 is amended to change Z¹ in Formula II to Z' and to insert the definition of Z'. See, e.g., page 35, of the specification.

New claims 49 and 50 are directed to the elected Group II. The addition of these new claims directed to the elected subject matter will not impose any additional burden on the Examiner.

Examiner's Requests

At page 2 of the Office Action, the Examiner requests that applicants' provide a definition of group Z¹ in claim 6. As mentioned above, claim 6 is amended to change Z¹ to Z' and to insert a definition of Z'.

Further, at the bottom of page 2 of the Office Action, the Examiner requests that applicants indicate support for the recitation that "Q is not CHOH." This feature of claim 1 is supported by the disclosure at, for example, page 7, line 5 and page 7, lines 18-19 of the specification.

See also *In re Johnson et al.*, 194 USPQ 187 (CCPA 1977), wherein an applicant amended a patent claim to add a proviso excluding subject matter disclosed within in its application. The Court ruled that the amendment did not create an artificial subgenus and did not constitute new matter.

Election

The most recent Restriction now divides the claims into 26 groups. In response to the Restriction, applicants hereby elect Group II, wherein R₁ and R₂ are together a methylene group, V and W are together a double bond, and R₃ and R₄ are each H or alkyl. However, this further Restriction is respectfully traversed for the reasons presented below.

Examiner's Assertions Regarding Prolonging Prosecution

At page 11 of the Office Action, the Examiner states that she "does not understand why Applicants choose to prolong the prosecution of this Application" and that "to further prosecution and simplify issues, Applicants must elect a group according to the rules of PCT Rule 13.1 and 13.2."

Contrary to the Examiner's comments, applicants respectfully submit that the Examiner's actions, not that of applicants', have prolong prosecution. For example, Applicants filed an Appeal Brief in the instant application on September 18, 2002. Rather than issuing the requisite Examiner's Answer, the Examiner decided to withdraw the application from Appeal and restart prosecution, noting that applicants' arguments were "found persuasive therefore rejection is withdrawn." (Office Action of December 2, 2002). Clearly applicants' actions in arguing against rejections which were subsequently withdrawn by the Examiner can not be characterized as prolonging prosecution. Further, prior to this restarting of prosecution, claim 1 was not split into more than one group.

In this application, the first Restriction/Election was issued on September 12, 2000 in which the claims were divided into two groups and an election of species requirement was made. Applicants had already responded telephonically to this Restriction/Election prior to the September 12, 2000 Office Action.

Then, after applicants filed a Reply to the Office Action of December 2, 2002 (which reopened prosecution), the Examiner issued a second Restriction Requirement on August 13, 2003. Almost three years later and after progressing through prosecution to the point of filing an Appeal Brief, the Examiner issued this second Restriction in which the claims were divided into 15 groups. In this Restriction, claims 8-11, which were originally included in the initially elected group, were now separated into four individual groups and claim 1, which was also originally included in the initially elected group, was itself divided among four groups (i.e., groups I, II, XIV, and XV). Applicants responded to this second Restriction by filing an election on October 14, 2003.

Then, almost a year after the Second Restriction and almost four years after the First Restriction/Election, the Examiner now issues a Third Restriction dividing the claims into 26 groups in which claim 1 is split among 16 groups (i.e., groups I, II, and XIII-XXVI). At the same time, the Examiner asserts that applicants have hindered prosecution "by refusing to elect a single invention, adding new claims after almost every Office Action, and arguing that the addition of new claims after almost every Office Action is justified as well as arguing that the restriction/election is incorrect."

Firstly, applicants have responded to each of the restrictions/elections by electing one of the groups specified by the Examiner and/or electing a specific species. Applicants have never "refused to elect a single invention."

Secondly, the addition of new claims is a right of the applicants and therefore is justified. Addition of such new claims is particularly justified when the Examiner keeps changing the scope of subject matter to be examined. Also, the addition of new claims does not necessarily require a new Restriction Requirement. For example, the initial Restriction grouped all compound claims dependent on claim 1 together (only claims 12 and 13 were restricted out as being directed to intermediate compounds). Furthermore, the initial Restriction grouped the "use" claims (now converted to method claims) together with compound claim 1. Thus, adding new compound claims dependent on claim 1 and/or new methods claims directed to uses of the compounds of claim 1 did not change the basis of the initial Restriction. Even if the addition of new claims involved inventions considered "new" in comparison to those set forth in the initial Restriction (which they did not), then the Examiner could have merely restricted out those claims on grounds of election by original presentation (MPEP §821.03).

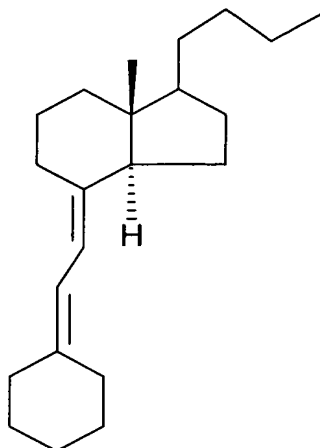
As for applicants arguing that the restriction is improper, this is clearly within applicants' rights. Moreover, applicants still maintain that the Restriction(s) are improper, as discussed further below. If the Examiner is not persuaded by applicants' arguments to withdraw the Restriction, the Examiner can easily make the Restriction final and permit the applicants to petition the Restriction.

Traversal of the most Recent Restriction

In this third Restriction, method claims 8-11 and 15-18 are each divided into individual Groups, i.e., Groups III, IV, V, VI, IX, X, XI, and XII, respectively. Applicants refer to the arguments presented in their response to the Second Restriction/Election requirement filed October 14, 2003.

In the Restriction, the Examiner reproduces PCT Rules 13.1, 13.2 13.3., and 13.4. However, the Examiner does not comment on applicants' prior arguments concerning the Annex of the PCT. Annex B, Part 1, section (e) states that Rule 13 is to be construed as permitting the inclusion in the same application claims directed to products, method of making, and method of use.

As for the compound claims, Annex B, Part 1, section (f) describes the procedure for handling Markush claims. The compounds of applicants' claims have at least one common property or utility, and they share a significant common structure represented by the following formula:



Furthermore, these compounds all belong to a recognized class of compounds, i.e., derivatives of Vitamin D, as can be seen from the prior art of record. Thus, unity of invention exists with respect to applicants' compound claims.

Further, Annex B, Part 1, section (f) states that merely because alternatives within a Markush grouping can be separately classified does not, by itself, justify a finding of lack of unity. Moreover, upon finding of a member of the Markush group within the prior art, the Examiner can reconsider unity of invention, but such reconsideration "does not necessarily imply that an objection for lack of unity shall be raised."

As for PCT Rule 13.4, the number of dependent claims in applicants' application is not unreasonable, in light of the subject matter involved and the circumstances of the present prosecution.

Turning to the compound groups, XVIII, XXII, and XXVI are identical with groups XVI, XX, and XXIV, respectively. Thus, restriction between groups XVIII, XXII, and XXVI, and groups XVI, XX, and XXIV, respectively, should be withdrawn.

Also, groups XVII, XXI, and XXV are identical with groups XV, XIX, and XXIII, respectively, except that the characterization of these groups is that groups XVII, XXI, and XXV refer to "vitamin D compounds" whereas groups XV, XIX, and XXIII refer simply to "compounds." This difference in characterization is meaningless since all of these groups include claim 1, which in its' preamble refers to a vitamin D compound. Thus, the subject

matter of groups XVII, XXI, and XXV is the same as that of groups XV, XIX, and XXIII, respectively, and restriction between these groups should be withdrawn.

The only difference between Groups I and II, Groups XIV and XIII, Groups XV and XVI, Groups XVII and XVIII, Groups XIX and XX, Groups XXI and XXII, Groups XXIII and XXIV, and Groups XXV and XXVI, are the definitions of R1 and R2, i.e., both hydrogen versus together being methylene. These are common alternative groups for this position, well recognized within the art. See, e.g., US 5,585,368, US 5,700,791, US 6,372,731 and US 6,376,480, all of record. Such an alternative does not justify an objection to unity of invention, especially since such a large relative portion of the structure of the compounds remains unchanged. This restriction between these groups should be withdrawn.

Similarly, dividing up the subject matter on the basis of the small class of alternatives for groups R3 and R4 does not justify an objection to unity of invention, especially since such a large relative portion of the structure of the compounds remains unchanged. Also, the Restriction presents no rationale as to why compound claim 19 is treated as a separate Group, rather than included with the Groups directed to claim 1. Thus, restriction between all of the compound groups should be withdrawn.

It is also noted that the various groups often overlap because of the possibility of R3 and R4 being H. Finally, it is noted that claim 1, for example, includes the possibility that V can be a hydroxyl group while W is H. Yet, despite the fact that the claims are now allegedly split into 26 allegedly "different" groups, none of these groups include this subject matter. Applicants respectfully request that, at the very least, all of groups I, II, and XIII-XXVI be expanded to include this definition of groups V and W.

For the reasons set forth above, withdrawal of the Restriction and examination of all pending claims is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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